

REMARKS

In this communication, Applicants have amended Claim 7 and canceled Claims 8-13. No new matter is introduced. Claims 7 and 32 are pending. Allowance of all pending claims is respectfully requested.

Rejections under 35 U.S.C. § 112

Claims 7-8 and 32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reasons stated on page 2 of the Office Action. Specifically, the Office Action alleges that the term “vector system” implies method steps and that it is unclear whether both “arms” are on a vector. Claim 7 has been amended to recite a “cloning system.” The Office Action also alleges that the term “said target nucleotide” lacks antecedent basis. Claim 7 has been amended to recite “said target polynucleotide,” as proposed by the Examiner. Claim 8 has been canceled.

Applicants respectfully submit that the grounds for the 35 U.S.C. § 112, second paragraph, rejection have been obviated. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 7-8 and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,348,886 to Lee et al. (hereinafter “Lee”) for reasons stated on pages 3-4 of the Office Action. Applicants respectfully traverse the rejection.

For anticipation under 35 U.S.C. § 102, the reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” (MPEP § 706.02). “A claim is anticipated only if each and every element as

set forth in the claim, either expressly or inherently described, in a single prior art reference.”

Verdegaal Bros. V. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent Claim 7, as amended, is directed to a composition comprising a cloning system for capture, cloning, manipulation, production and delivery of large nucleic acids to a target cell. The vector comprises (a) a first arm having a first selectable marker, a first cyclization element, and a first segment homologous to the 5' terminus of a target polynucleotide; and (b) a second arm having a second selectable marker, a second cyclization element, and a second segment homologous to the 3' terminus of the target polynucleotide, wherein the target polynucleotide is a polynucleotide of a virus and said virus is selected from the group consisting of adenovirus, adeno-associated virus, pox virus, papova virus and herpes virus.

Lee is directed to a baculovirus shuttle vector (bacmid) that can replicate in *E. coli* as a plasmid and can infect susceptible insect cells. The bacmid is a recombinant virus that contains a mini-F replicon, a kanamycin resistance marker, and attTn7, the target site for the bacterial transposon Tn7. Expression cassettes comprising a baculovirus promoter driving expression of a foreign gene flanked by the left and right ends of Tn7 can transpose to the target bacmid in *E. coli* when Tn7 transposition functions are provided in trans by a helper plasmid. The foreign gene is expressed when the resulting composite bacmid is introduced into insect cells. In other words, Lee does not describe a vector for delivery of large nucleic acids (as required by Claim 7), but a means to introduce a transgene into a target cell. Lee also does not describe or suggest a cloning system where the target polynucleotide is from a virus selected from the group consisting of adenovirus, adeno-associated virus, pox virus, papova virus and herpes virus.

In addition, Lee does not teach or suggest a “cyclization element.” The Office Action alleges that the preferential target site for insertion of a transposon, i.e., attTn7-phoS and attTn7-glmS, can be considered as “cyclization elements.” Applicants respectfully disagree. The term

“cyclization element,” as defined by the specification, denotes a nucleic acid capable of promoting the circularization of the arms of interest into a recombinant vector. Examples of such elements include Alu sequences, Lox sites, and FLP sequences. (Page 18, line 24 to page 19, line 6). The attTn7 elements on the baculovirus shuttle vector of Lee serve as preferential target sites but not as “cyclization elements.” In fact, all the vectors described in Lee are circularized plasmids (see Figures 1-3) and there is no need to use a “cyclization element” in these vectors. Accordingly, Applicants respectfully submit that Lee does not teach every aspect of the claimed invention, and therefore, independent Claim 7 is not anticipated by Lee. Applicants further submit that Claim 32 is not anticipated by Lee because it depends from Claim 7. Withdrawal of the 35 U.S.C. § 102 rejection to Claims 7 and 32 is respectfully requested. Claim 8 has been canceled. Rejection to Claim 8 is now moot.

Rejections under 35 U.S.C. § 103

Claims 7-13 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee for reasons stated on pages 4-5 of the Office Action. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all of the claim limitations. In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142. Moreover, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art (see MPEP § 2143.01; and In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992)).

As discussed above, Lee is quite different from the invention claimed in independent Claim 7. Lee does not describe a vector for “delivery of large nucleic acids,” as recited in Claim 7, but a means to introduce a transgene into a target cell. Lee does not describe or suggest a cloning system where the target polynucleotide is from a virus selected from the group consisting of adenovirus, adeno-associated virus, pox virus, papova virus and herpes virus. Moreover, Lee does not teach or suggest a “cyclization element,” nor does it provide any motivation or desirability to one skilled in the art to modify the baculovirus vector by including a cyclization element. Accordingly, Applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of obviousness. Withdrawal of the 35 U.S.C. § 103(a) rejection to Claim 7 is respectfully requested.

If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. In re Fine, 5 USPQ2d 1596 (Fed Cir. 1988). Accordingly, dependent Claim 32 is patentable because it depends from Claim 7 and define additional patentable subject matter. Withdrawal of the 35 U.S.C. § 103 rejection to Claim 32 is respectfully requested.

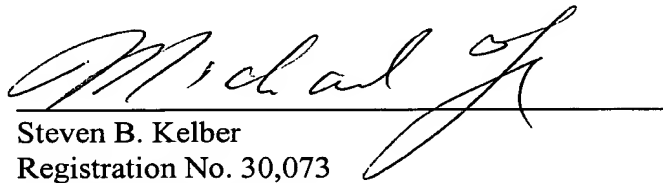
Claims 8-13 have been canceled by this amendment. Rejection to these claims are now moot.

CONCLUSION

In view of the foregoing remarks, favorable reconsideration of all pending claims is requested. Applicants respectfully submit that this application is in condition for allowance and requests that a notice of allowance be issued. Should the Examiner believe that anything further is required to expedite the prosecution of this application or further clarify the issues, the Examiner is requested to contact Applicants' representative at the telephone number listed below.

Respectfully submitted,

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FULL TEXT OF CASES (USPQ2D)

All Other Cases

Verdegaal Brothers Inc. v. Union Oil Company of California (CA FC) 2 USPQ2d 1051 (3/12/1987)

Verdegaal Brothers Inc. v. Union Oil Company of California (CA FC) 2 USPQ2d 1051

Verdegaal Brothers Inc. v. Union Oil Company of California

U.S. Court of Appeals Federal Circuit
2 USPQ2d 1051

Decided March 12, 1987

No. 86-1258

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- Prior art (§ 115.0703)

Federal district court erred in denying patent infringement defendant's motion for judgment n.o.v., in view of evidence demonstrating that claims for making urea-sulfuric acid fertilizer, including claims that reaction be conducted in "heat sink" of recycled fertilizer to prevent high temperature buildup, were anticipated by prior art patent that specifically detailed process for making such urea-sulfuric acid products and that explicitly taught that base or "heel" of recycled fertilizer can be used to make more of product, even if patentee of prior art did not recognize that heel functioned as heat sink, since heat sink property was inherently possessed by heel.

Particular patents -- Fertilizers

4,310,343, Verdegaal and Verdegaal, Process for Making Liquid Fertilizer, holding of validity and infringement reversed.

Case History and Disposition:

Page 1051

Appeal from District Court for the Eastern District of California, Coyle, J.

Action by Verdegaal Brothers Inc., William Verdegaal, and George Verdegaal, against Union Oil

Company of California, and Brea Agricultural Services Inc., for patent infringement. From decision denying defendants' motion for judgment notwithstanding the verdict, defendants appeal. Reversed.

Attorneys:

Andrew J. Belansky of Christie, Parker & Hale (David A. Dillard, with him on the brief), all of Pasadena, Calif., for appellants.

John P. Sutton of Limbach, Limbach & Sutton (Michael E. Dergosits, with him on the brief), all of San Francisco, Calif., for appellees.

Judge:

Before Markey, Chief Judge, and Davis and Nies, Circuit Judges.

Opinion Text

Opinion By:

Nies, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the '343 patent involves the chemical reaction between urea

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and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer -- known as a "heel" -- can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
 - a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
 - b. adding water to the heat sink in an amount not greater than 15% of the end product,
 - c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
 - d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.

2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. §§102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under Fed. R. Civ. P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid under sections 102 and 103. The district court denied the motion without opinion.

II

ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

III

Standard of Review

When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed. Cir.), *cert. denied*, 469 U.S. 871 [224 USPQ 520] (1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed. Cir. 1983). A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics*, 727 F.2d at 1513, 220 USPQ at 936; *Connell*, 722 F.2d at 1546, 220 USPQ at 197.

To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir.), *cert. denied*, 469 U.S. 857 [225 USPQ 792] (1984). *Railroad Dynamics*, 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938); *Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 371 n.10, 218 USPQ 678, 684 n.10 (Fed. Cir. 1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed. Cir. 1984).

Our precedent holds that the presumption of validity afforded a U.S. patent by 35

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U.S.C. § 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir.), *cert. denied*, 469 U.S. 821 [224 USPQ 520] (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and

convincing that reasonable jurors could only conclude that the claims in issue were invalid. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 935.

Anticipation

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed. Cir. 1984); *Connell*, 722 F.2d at 1548, 220 USPQ at 198; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 [224 USPQ 520] (1984). Union Oil asserts that the subject claims of the '343 patent are anticipated under 35 U.S.C. § 102(e) 1 by the teachings found in the original application for U.S. Patent No. 4,315,783 to Stoller, which the jury was instructed was prior art.

From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer. 2

The Stoller specification, beginning at column 7, line 30, discloses:

Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaaal presented no evidence to the contrary.

Verdegaaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaaal to rely on that distinction. *See SSIH*, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

Verdegaaal next argues that the testimony of Union Oil's experts with respect to what

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Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.

[1] Verdegaaal raises several variations of an argument, all of which focus on the failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high temperature caused by

the exothermic reaction, and that the heel could function as a heat sink. 3 In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. See *In re Oelrich* , 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart* , 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. §§ 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art. . . . This conclusion finds support in *In re Wertheim* , 646 F.2d 527 [209 USPQ 554] (CCPA 1981), and 1 Chisum on Patents §3.07[3].

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?

A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. 4 Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. See Fed. R. Civ. P. 51; *Weinar v. Rollform Inc.* , 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed. Cir. 1984), *cert. denied* , 105 S.Ct. 1844 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.* , 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed. Cir.), *cert. denied* , 469 U.S. 1038 (1984). 5 After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and

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cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. 6 In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

REVERSED

Footnotes

Footnote 1. Section 102(e) provides:

A person shall be entitled to a patent unless--

....
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

....
Footnote 2. Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

Footnote 3. There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

Footnote 4. The jury instruction read:

Stoller filed two patent applications -- an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

Footnote 5. Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

Footnote 6. It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any *issue* which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. *See Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 934.

- End of Case -

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ISSN 1526-8535

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FULL TEXT OF CASES (USPQ2D)

All Other Cases

In re Vaeck (CA FC) 20 USPQ2d 1438 (10/21/1991)

In re Vaeck (CA FC) 20 USPQ2d 1438

In re Vaeck

U.S. Court of Appeals Federal Circuit
20 USPQ2d 1438

Decided October 21, 1991

No. 91-1120

Headnotes

PATENTS

1. Patentability/Validity - Obviousness - Combining references _ (§ 115.0905)

Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure.

2. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions _ (§ 115.0903.03)

Patent and Trademark Office has failed to establish prima facie obviousness of claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, since prior art does not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill reasonable expectation of success in doing so; expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious expression of unrelated genes in cyanobacteria for unrelated purposes.

3. Patentability/Validity - Specification - Enablement _ (§ 115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure - Judicial review - Standard of review - Patents (§ 410.4607.09)

Specification must, in order to be enabling as required by 35 USC 112, first paragraph, teach person skilled in art to make and use invention without "undue experimentation," which does not preclude some experimentation; enablement is question of law which is reviewed independently on appeal, although such determination is based upon underlying factual findings which are reviewed for clear error.

PATENTS

4. Patentability/Validity - Specification - Enablement (§ 115.1105)

Patent and Trademark Office did not err in rejecting, as non-enabling pursuant to 35 USC 112, first paragraph, claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants' filing date, as well as limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention, since there is no reasonable correlation between narrow disclosure in applicants' specification and broad scope of protection sought in claims encompassing gene expression in any and all cyanobacteria.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/021,405, filed March 4, 1987, by Mark A. Vaeck, Wipa Chungjatupornchai, and Lee McIntosh (hybrid genes incorporating a DNA fragment containing a gene coding for an insecticidal protein, plasmids, transformed cyanobacteria expressing such protein and method for use as a biocontrol agent). From decision rejecting claims 1-48 and 50-52 as unpatentable under 35 USC 103, and rejecting claims 1-48 and 50-51 for lack of enablement, applicants appeal. Affirmed and part and reversed in part; Mayer, J., dissents with opinion.

Attorneys:

Ian C. McLeod, Okemos, Mich., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor and Richard E. Schafer, associate solicitor, with him on brief), for appellee.

Judge:

Before Rich, Archer, and Mayer, circuit judges.

Opinion Text

Opinion By:

Rich, J.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 USC 103, as well as the rejection of claims 1-48 and 50-51 under 35 USC 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

BACKGROUND

A. The Invention

The claimed invention is directed to the use of genetic engineering techniques 1 for production of proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.

As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote 2 kingdom, the

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cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within transformed 3 cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.

More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing 4 the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.

The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:

(a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and

(b) at least one DNA fragment coding for an insecticidally active protein produced by a *Bacillus* strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein, the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers. 5 Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52

recites a particular plasmid that appellants have deposited.

B. Appellants' Disclosure

In addition to describing the claimed invention in generic terms, appellants' specification discloses two particular species of *Bacillus* (*B. thuringiensis*, *B. sphaericus*) as sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Aphanocapsa*, *Gloeocapsa*, *Nostoc*, *Anabaena* and *Ffremyllia*) as useful hosts.

The working examples relevant to the claims on appeal detail the transformation of a single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis*, linked to (2) a particular promoter, the P_L promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda P_L promoter.

C. The Prior Art

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.

The focus of Dzelzkalns, 6 the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT). 7 Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

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Sekar I, 8 Sekar II, 9 and Ganesan 10 collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium*, *B. subtilis* and *E. coli*.

Friedberg 11 discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O_LP_L operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth of overexpressed, highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis*"

Miller 12 compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases 13 purified from two different species of cyanobacteria (*Fremyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli*.

Nierzwicki-Bauer 14 identifies in the cyanobacterium *Anabaena* 7120 the start site for transcription of the gene encoding *rbc* L, the large subunit of the enzyme ribulose-1, 5-bisphosphate carboxylase. It reports that the nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.

Chauvat 15 discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.

Reiss 16 studies expression in *E. coli* of various proteins formed by fusion of certain foreign DNA sequences with the *neo* gene.

Kolowsky 17 discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.

Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding

Bacillus proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

D. The Grounds of Rejection

1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 USC 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the

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expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was prima facie obvious.

Additional rejections were entered against various groups of dependent claims which we need not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above. The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 USC 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) 19 and (z) 20 as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. With respect to unpredictability, the examiner stated that the cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Nostoc*, *Anabaena*, etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of procaryotes is high....

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)."

OPINION

A. Obviousness

We first address whether the PTO erred in rejecting the claims on appeal as prima facie obvious within the meaning of 35 USC 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).

[1] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

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[2] We agree with appellants that the PTO has not established the prima facie obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in cyanobacteria of a chimeric gene encoding an insecticidally active protein, or convey to those of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed bacterial hosts, nowhere do these references disclose or suggest expression of such genes in transformed cyanobacterial hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both procaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as procaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Procaryotae. ²¹ Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities.

For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes. Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous *genes involved in photosynthesis* (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among procaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins.

In *O'Farrell*, this court affirmed an obviousness rejection of a claim to a method for

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producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 USPQ2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. *Id.* at 901, 7 USPQ2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that

the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.

....

... Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 USPQ2d at 1679-80.

In contrast with the situation in *O'Farrell*, the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

B. Enablement

[3] The first paragraph of 35 USC 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 USPQ2d at 1404.

Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. *See id.* at 735, 8 USPQ2d at 1402. In response to the § 112 rejection, appellants assert that their invention is "pioneering," and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled

microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable."

Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

[4] Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification).

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22 Accordingly, we affirm the § 112 rejection as to those claims.

In so doing we do *not* imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, 23 to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. *See Fisher*, 427 F.2d at 839, 166 USPQ at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue experimentation.

Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depend from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 USC 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 USC 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.

AFFIRMED-IN-PART, REVERSED-IN-PART

Footnotes

Footnote 1. Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988), and are not repeated here.

Footnote 2. All living cells can be classified into one of two broad groups, procaryotes and eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus wherein their DNA resides.

Footnote 3. "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.

Footnote 4. "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.

Footnote 5. In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.

Footnote 6. *Nucleic Acids Res.* 8917 (1984).

Footnote 7. Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.

Footnote 8. *Biochem. and Biophys. Res. Comm.* 748 (1986).

Footnote 9. *Gene* 151 (1985).

Footnote 10. *Mol. Gen. Genet.* 181 (1983).

Footnote 11. *Mol. Gen. Genet.* 505 (1986).

Footnote 12. *J. Bacteriology* 246 (1979).

Footnote 13. RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.

Footnote 14. *Proc. Natl. Acad. Sci. USA* 5961 (1984).

Footnote 15. *Mol. Gen. Genet.* 185 (1986).

Footnote 16. *Gene* 211 (1984).

Footnote 17. *Gene* 289 (1984).

Footnote 18. Denotes different species or organism.

Footnote 19. MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part: In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure....

Footnote 20. MPEP 796.03(z), "Undue Breadth," provides in part: In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol*, 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield*, 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." ...

Footnote 21. *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Procaryotae"). Procaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom; Division; Class; Order; Family; Genus; Species. 3 *Bergey's Manual of Systematic Bacteriology* 1601 (1989).

Footnote 22. The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan*, 559 F.2d 595, 605-07, 194 USPQ 527, 536-38 (CCPA 1977). See also *United*

States Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568-69, 15 USPQ2d 1039, 1047-48 (Fed. Cir. 1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), *cert. dismissed*, — U.S. —, 111 S. Ct. 1434 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher*'s analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher*, 427 F.2d at 839, 166 USPQ at 24.

Footnote 23. The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

Dissenting Opinion Text

Dissent By:

Mayer, J., dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987); *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 USPQ 668, 671 (Fed. Cir. 1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if thought this opinion were more persuasive than the board's, I could not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 USPQ2d 1031, 1037 (Fed. Cir. 1991). And "[w]here there are two permissible views of

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the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

- End of Case -

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FULL TEXT OF CASES (USPQ2D)

All Other Cases

In re Jones (CA FC) 21 USPQ2d 1941 (2/28/1992)

In re Jones (CA FC) 21 USPQ2d 1941

In re Jones**U.S. Court of Appeals Federal Circuit**
21 USPQ2d 1941**Decided February 28, 1992****No. 91-1380****Headnotes****PATENTS****1. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions _**
(§ 115.0903.03)

Claimed novel salt of acid commonly known as "dicamba" is not so closely related in structure to substituted ammonium salts disclosed in prior patent as to be prima facie obvious, since claimed salt is primary amine with ether linkage, whereas diethanolamino salt disclosed in reference patent is secondary amine without ether linkage, since claimed salt is plainly acyclic or linear, whereas morpholino salt, which is only substituted ammonium salt of dicamba with ether linkage disclosed in reference patent, is cyclic in structure, and since isopropylamino salt disclosed in reference patent is primary amine, but has iso-structure quite different from that of claimed salt.

2. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions _
(§ 115.0903.03)

Claimed novel salt of acid commonly known as "dicamba" cannot be held prima facie obvious in view of salts disclosed in prior patent, even though claimed salt is member of genus of substituted ammonium salts broadly disclosed in reference patent, since reference discloses potentially infinite genus of "substituted ammonium salts" of dicamba, and lists several such salts, but does not specifically disclose salt claimed in application, and since claimed salt is not sufficiently similar to those disclosed in reference as to render it prima facie obvious.

3. Patentability/Validity -- Obviousness -- Combining references _
(§ 115.0905)

Contention that one skilled in herbicidal art would have been motivated to use, with acid commonly known as "dicamba," substituted ammonium salt such as that disclosed in two prior references does

not warrant holding that claimed substituted ammonium salt of dicamba for use as herbicide is *prima facie* obvious, since there is no suggestion for combining disclosures of those references either in references themselves, which are directed to shampoo additives and production of morpholine, respectively, or in knowledge generally available to those skilled in art.

Case History and Disposition:

Page 1941

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Rita S. Jones, Michael T. Chirchirillo and Johnny L. Burns, serial no. 07/099,279 (the 2-(2'-aminoethoxy)-ethanol salt of dicamba). From decision upholding rejection of only claim in application, applicants appeal. Reversed.

Attorneys:

Melvyn M. Kassenoff, East Hanover, N.J. (Gerald D. Sharkin and Richard E. Villa, East Hanover; Joanne M. Giesser, Palo Alto, Calif., with him on brief), for appellant.

Harris A. Pitlock, associate solicitor (Fred E. McKelvey, solicitor, with him on brief; Richard E. Schafer, of counsel), for appellee.

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Judge:

Before Rich, Archer, and Clevenger, circuit

Opinion Text

Opinion By:

Rich, J.

Rita S. Jones et al. (collectively Jones) appeal from the April 15, 1991 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), Appeal No. 90-1920, sustaining the rejection of claim 1, the only claim of application Ser. No. 07/099,279, titled "The 2-(2'-Aminoethoxy) -- Ethanol Salt of Dicamba," as unpatentable under 35 USC 103. We conclude that the PTO has not presented a *prima facie* case of obviousness, and therefore *reverse*.

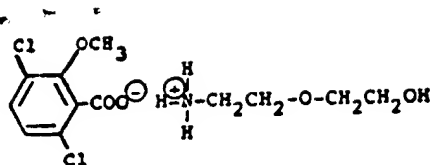
The Invention

The Claimed invention is a novel salt of 2-methoxy-3, 6-dichlorobenzoic acid, which acid is commonly referred to as "dicamba." A known herbicide, dicamba has typically been sold in the form of its known dimethylamine salt.

The sole claim of the application on appeal reads:

1. The 2-(2'-aminoethoxy) ethanol salt of dicamba.

The claimed salt has the following structure:



The Rejection

Claim 1 stands rejected as obvious in view of the combined teachings of the following references:

Richter, U.S. Patent No. 3,013,054, Dec. 12, 1961

Moyle et al., U.S. Patent No. 3,056,669, Oct. 2, 1962

Balassa, U.S. Patent No. 3,725,031, Apr. 3, 1973

Zorayan et al., 88 *Chem. Abstracts* No. 52300j, 1978

Wideman, 86 *Chem. Abstracts* No. 43711a, 1977

Richter, which all agree is the closest prior art, discloses dicamba in free acid, ester, and salt forms, for use as a herbicide. Among the salt forms disclosed are substituted ammonium salts, a genus which admittedly encompasses the claimed salt. Richter does not specifically disclose the claimed 2-(2'-aminoethoxy) ethanol salt, however. Most notably, Richter discloses (emphasis and bracketed word ours):

Compositions in which X is substituted ammonium are amine salts of 2-methoxy-3, 6-dichlorobenzoic acid [dicamba] and are prepared by the addition of the free acid to various amines. Typical amines which can be used to prepare such amine salts are dimethylamine, trimethylamine, triethylamine, diethanolamine, triethanolamine, isopropylamine, morpholine, and the like. *The resulting products are, respectively, the dimethylamino, trimethylamino, triethylamino, diethanolamino, triethanolamino, isopropylamino, and morpholino salts of 2-methoxy-3, 6-dichlorobenzoic acid.*

Zorayan teaches the amine (H [inf 2] N (CH [inf 2] CH [inf 2] O) [inf 2] H) used to make the claimed salt, as well as the use of that amine in the preparation of surfactants for shampoos, bath preparations, and emulsifiers.

Wideman also teaches the amine disclosed in Zorayan.

The content of the remaining references is unnecessary to our decision.

The Board upheld the examiner's rejection of claim 1 as obvious, finding that the claimed 2-(2'-aminoethoxy) ethanol salt of dicamba and the diethanolamine salt of dicamba specifically disclosed by Richter were "closely related in structure," and that based upon the expectation that "compounds similar in structure will have similar properties," a *prima facie* case of obviousness had arisen. The Board found that Jones' rebuttal evidence (Rule 132 declarations and data reported in the specification) failed to "compare the claimed subject matter with the closest prior art," and accordingly did not serve to rebut the *prima facie* case. This appeal followed.

Analysis

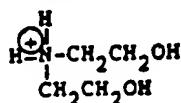
The Solicitor contends that the claimed salt falls within the genus of substituted amine salts of dicamba disclosed by Richter, and that, like Richter's genus, the claimed compound has herbicidal activity. Thus, the Solicitor urges, under the circumstances of this case, (1) the genus/species relationship and (2) the common utility of the claimed and prior art compounds support the Board's holding of *prima facie* obviousness. Moreover, the Solicitor adds, although the claimed compound is neither a homolog nor a position isomer of those salts specifically disclosed in Richter, it is structurally similar thereto, particularly the diethanolamino salt noted by the Board.

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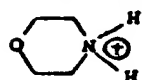
The question of "structural similarity" in chemical patent cases has generated a body of patent law unto itself. ¹ Particular types or categories of structural similarity without more have, in past cases, given rise to *prima facie* obviousness; see, e.g., *In re Dillon*, 919 F.2d 688, 692-94, 16 USPQ2d 1897, 1900-02 (Fed. Cir. 1990) (tri-orthoesters and tetra-orthoesters), *cert. denied*, ___ U.S. ___, 111 S. Ct. 1682 (1991); *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers);

In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) (adjacent homologs and structural isomers); *In re Hoch*, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970) (acid and ethyl ester). However, none of these types of structural similarity are involved here. And in any event, this court has previously stated that generalization is to be avoided insofar as specific structures are alleged to be *prima facie* obvious one from the other. *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985).

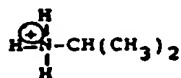
[1] On the basis of the record before us, we cannot sustain the Board's conclusion that the claimed salt and the diethanolamino salt disclosed by Richter are so "closely related in structure" as to render the former *prima facie* obvious in view of the latter. The claimed salt is a primary amine with an ether linkage. The diethanolamino salt disclosed by Richter is a secondary amine, without an ether linkage:



In addition, the only substituted ammonium salt of dicamba expressly disclosed by Richter having an ether linkage is the morpholino salt, which is *cyclic* in structure:



The claimed salt is, plainly, *a* cyclic; i.e., linear. Lastly, while the isopropylamino salt disclosed by Richter is a primary amine, as is the claimed salt, its iso- structure is quite different:



[2] The lack of close similarity of structure is not negated by the fact that the claimed salt is a member of Richter's broadly disclosed genus of substituted ammonium salts of dicamba. The Solicitor contends that "[t]he relative size of the genus disclosed by the prior art would not appear to be a controlling factor in determining whether a *prima facie* case of obviousness exists for a species encompassed within the described genus," citing *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 806-09, 10 USPQ2d 1843, 1845-48 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 110 S. Ct. 498 (1989). We decline to extract from *Merck* the rule that the Solicitor appears to suggest -- that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it. In *Merck*, at issue on appeal was whether claims to a composition of two diuretics, amiloride and hydrochlorothiazide, present in a particular "medically synergistic" weight ratio, would have been obvious in view of a specific prior art disclosure of amiloride in combination with hydrochlorothiazide, one of 1200 such combinations disclosed in the prior art reference. *Id.* at 806, 10 USPQ2d at 1845. Based on the facts before it, including evidence at trial that the experimentation needed to arrive at the claimed dosage was "nothing more than routine," *Id.* at 809, 10 USPQ2d at 1847, the court affirmed the trial court's determination of obviousness. In contrast, though Richter discloses the potentially infinite genus of "substituted ammonium salts" of dicamba, and lists several such salts, the salt claimed here is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it *prima facie* obvious. Every case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts.

[3] The Solicitor points out that, given the breadth of forms of dicamba (free acid, ester, or salt) disclosed by Richter as having herbicidal utility, one of ordinary skill in the art would appreciate that the dicamba group has significance with respect to imparting herbicidal activity to dicamba compounds. Thus, the Solicitor contends, one skilled in the art would have been motivated to use, with dicamba, substituted ammonium salts made from a known amine, such as the amine disclosed by Zorayan and Wideman, and would have expected such a salt to have herbicidal activity. Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some sug

gestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). We see no such suggestion in Zorayan, which is directed to shampoo additives, nor in Wideman, which teaches that the amine used to make the claimed compound is a byproduct of the production of morpholine. Nor does the broad disclosure of Richter fill the gap, for the reasons discussed above.

Conspicuously missing from this record is any *evidence*, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed 2-(2'-aminoethoxy) ethanol salt. *See Grabiak*, 769 F.2d at 731-32, 226 USPQ at 872 ("[I]n the case before us there must be adequate support in the prior art for the [prior art] ester/ [claimed] thioester change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant."): *In re Lahu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.")

Conclusion

We conclude that the PTO did not establish a *prima facie* case of obviousness, and thus did not shift to Jones the burden of coming forward with unexpected results or other objective evidence of non-obviousness. Accordingly, the decision of the Board is *REVERSED*.

Footnotes

Footnote 1. *See generally* Helmuth A. Wegner, "Prima Facie Obviousness of Chemical Compounds," 6 *Am. Pat. L. Assoc. O. J.* 271 (1978).

- End of Case -

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ISSN 1526-8535

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FULL TEXT OF CASES (USPQ2D)

All Other Cases

In re Fine (CA FC) 5 USPQ2d 1596 (1/26/1988)

In re Fine (CA FC) 5 USPQ2d 1596

In re Fine**U.S. Court of Appeals Federal Circuit**
5 USPQ2d 1596

Decided January 26, 1988

No. 87-1319

Headnotes**PATENTS****1. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)**

Patent and Trademark Office improperly rejected claimed invention for obviousness since nothing in cited references, either alone or in combination, suggests or teaches claimed invention, since there is consequently no support for PTO's conclusion that substitution of one type of detector for another in prior art system, resulting in claimed invention, would have been obvious, and since PTO therefore failed to satisfy its burden of establishing prima facie case of obviousness by showing some objective teaching or generally available knowledge that would lead one skilled in art to combine teachings of existing references.

2. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Obviousness is tested by what combined teachings of prior art references would have suggested to those of ordinary skill in art, not by whether particular combination of elements from such references might have been "obvious to try."

3. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)

Patent and Trademark Office erred, in rejecting as obvious system for detecting and measuring minute quantities of nitrogen compounds, by failing to recognize that appealed claims can be distinguished over combination of prior art references, in view of evidence demonstrating that prior art does not teach claimed temperature range, despite some overlap of preferred temperature ranges for claimed invention and prior art, since purposes of preferred temperature ranges are different and overlap is mere happenstance.

4. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Dependent claims are non-obvious under 35 USC 103 if claims from which they depend are non-obvious.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Application for patent by David H. Fine, Serial No. 512,374. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicant appeals. Reversed; Smith, circuit judge, dissenting with opinion.

Attorneys:

Morris Relson and Darby & Darby, New York, N.Y., (Beverly B. Goodwin with them on the brief) for appellant.

Lee E. Barrett, associate solicitor, Arlington, Va., (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Judge:

Before Friedman, Smith, and Mayer, circuit judges.

Opinion Text

Opinion By:

Mayer, J.

David H. Fine appeals from a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (Board) affirming the rejection of certain claims of his application, Serial No. 512,374, and concluding that his invention would have been obvious to one of ordinary skill in the art and was therefore unpatentable under 35 U.S.C. §103. We reverse.

Background

A. The Invention .

The invention claimed is a system for detecting and measuring minute quantities of nitrogen compounds. According to Fine, the system has the ability to detect the presence of nitrogen compounds in quantities as minute as one part in one billion, and is an effective means to detect drugs and explosives, which emanate nitrogen compound vapors even when they are concealed in luggage and closed containers.

The claimed invention has three major components: (1) a gas chromatograph which separates a gaseous sample into its constituent parts; (2) a converter which converts the nitrogen compound effluent output of the chromatograph into nitric oxide in a hot, oxygen-rich environment; and (3) a detector for measuring the level of nitric oxide. The claimed invention's sensitivity is achieved by combining nitric oxide with ozone to produce nitrogen dioxide which concurrently causes a detectable luminescence. The luminescence, which is measured by a visual detector, shows the level of nitric oxide which in turn is a measure of nitrogen compounds found in the sample.

The appealed claims were rejected by the Patent and Trademark Office (PTO) under 35 U.S.C. §103. Claims 60, 63, 77 and 80 were rejected as unpatentable over Eads, Patent No. 3,650,696 (Eads) in view of Warnick, et al., Patent No. 3,746,513 (Warnick). Claims 62, 68, 69, 79, 85 and 86 were rejected as unpatentable over Eads and Warnick in view of Glass, et al., Patent No. 3,207,585 (Glass).

B. The Prior Art .

1. Eads Patent .

Eads discloses a method for separating, identifying and quantitatively monitoring sulfur compounds. The Eads system is used primarily in "air pollution control work in the scientific characterization of odors from sulfur compounds."

The problem addressed by Eads is the tendency of sulfur compounds "to adhere to or react with the surface materials of the sampling and analytical equipment, and/or react with the liquid or gaseous materials in the equipment." Because of this, the accuracy

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of measurement is impaired. To solve the problem, the Eads system collects an air sample containing sulfur compounds in a sulfur-free methanol solution. The liquid is inserted into a gas chromatograph which separates the various sulfur compounds. The compounds are next sent through a pyrolysis furnace where they are oxidized to form sulfur dioxide. Finally, the sulfur dioxide passes through a measuring device called a microcoulometer which uses titration cells to calculate the concentration of sulfur compounds in the sample.

2. Warnick Patent .

Warnick is directed to a means for detecting the quantity of pollutants in the atmosphere. By measuring the chemiluminescence of the reaction between nitric oxide and ozone, the Warnick device can detect the concentration of nitric oxide in a sample gaseous mixture.

Warnick calls for "continuously flowing" a sample gaseous mixture and a reactant containing ozone into a reaction chamber. The chemiluminescence from the resulting reaction is transmitted through a light-transmitting element to produce continuous readouts of the total amount of nitric oxide present in the sample.

3. Glass Patent.

The invention disclosed in Glass is a device for "completely burning a measured amount of a substance and analyzing the combustion products." A fixed amount of a liquid petroleum sample and oxygen are supplied to a flame. The flame is then spark-ignited, causing the sample to burn. The resulting combustion products are then collected and measured, and from this measurement the hydrogen concentration in the sample is computed.

C. The Rejection .

The Examiner rejected claims 60, 63, 77 and 80 because "substitution of the [nitric oxide] detector of Warnick for the sulfur detector of Eads would be an obvious consideration if interested in nitrogen compounds, and would yield the claimed invention." He further asserted that "Eads teaches the [claimed] combination of chromatograph, combustion, and detection, in that order. . . . Substitution of detectors to measure any component of interest is well within the skill of the art." In rejecting claims 62, 68, 69, 79, 85 and 86, the Examiner said, "Glass et al. teach a flame conversion means followed by a detector, and substitution of the flame conversion means of Glass et al. for the furnace of Eads would be an obvious equivalent and would yield the claimed invention." The Board affirmed the Examiner's rejection.

Discussion

A. Standard of Review .

Obviousness under 35 U.S.C. §103 is " 'a legal conclusion based on factual evidence.' " *Stratoflex*,

Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983) (quoting *Stevenson v. Int'l Trade Comm'n*, 612 F.2d 546, 549, 204 USPQ 276, 279 (CCPA 1979)). Therefore, an obviousness determination is not reviewed under the clearly erroneous standard applicable to fact findings, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983); it is "reviewed for correctness or error as a matter of law." *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

To reach a proper conclusion under §103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of *all* the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been obvious at *that* time to *that* person. 35 U.S.C. §103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595-96 (Fed. Cir. 1987).

B. Prima Facie Obviousness .

Fine says the PTO has not established a *prima facie* case of obviousness. He contends the references applied by the Board and Examiner were improperly combined, using hindsight reconstruction, without evidence to support the combination and in the face of contrary teachings in the prior art. He argues that the appealed claims were rejected because the PTO thought it would have been "obvious to try" the claimed invention, an unacceptable basis for rejection.

[1] We agree. The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. See *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984). It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Lulu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984); see also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*,

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776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). This it has not done. The Board points to nothing in the cited references, either alone or in combination, suggesting or teaching Fine's invention.

The primary basis for the Board's affirmance of the Examiner's rejection was that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. The Board reiterated the Examiner's bald assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art," but neither of them offered any support for or explanation of this conclusion.

Eads is limited to the analysis of sulfur compounds. The particular problem addressed there is the difficulty of obtaining precise measurements of sulfur compounds because of the tendency of sulfur dioxide to adhere to or react with the sampling analytic equipment or the liquid or gaseous materials in the equipment. It solves this problem by suggesting that the gaseous sample containing sulfur compounds be absorbed into sulfur-free methanol and then inserted into a gas chromatograph to separate the sulfur compounds.

There is no suggestion in Eads, which focuses on the unique difficulties inherent in the measurement of sulfur, to use that arrangement to detect nitrogen compounds. In fact, Eads says that the presence of nitrogen is undesirable because the concentration of the titration cell components in the sulfur detector is adversely affected by substantial amounts of nitrogen compounds in the sample. So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention. See *W. L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983) (error to find obviousness where references "diverge from and teach away from the invention at hand"). In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads system. Accordingly, there is no suggestion to combine Eads and Warnick.

Likewise, the teachings of Warnick are inconsistent with the claimed invention, to some extent. The Warnick claims are directed to a gas stream from engine exhaust "continuously flowing the gaseous mixtures into the reaction chamber" to obtain "continuous readouts" of the amount of nitric oxide in the sample. The other words, it contemplates measuring the total amount of nitric oxide in a continuously flowing gaseous mixture of unseparated nitrogen constituents. By contrast, in Fine each nitrogen compound constituent of the gaseous sample is retained in the Chromatograph for an individual time period so that each exists in discrete, time-separated pulses. * By this process, each constituent may be both identified by its position in time sequence, and measured. The claimed system, therefore, diverges from Warnick and teaches advantages not appreciated or contemplated by it.

Because neither Warnick nor Eads, alone or in combination, suggests the claimed invention, the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. *ACS Hosp. Sys.*, 732 F.2d at 1575-77, 221 USPQ at 931-33. The Eads and Warnick references disclose, at most, that one skilled in the art might find it obvious to try the claimed invention. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *In re Geiger*, 815 F.2d 868, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978).

[2] Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none. Instead, the Examiner relies on hindsight in reaching his obviousness determination.

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But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W. L. Gore*, 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

C. Advantage Not Appreciated by the Prior Art .

[3] The Board erred not only in improperly combining the Eads and Warnick references but also in failing to appreciate that the appealed claims can be distinguished over that combination. A material limitation of the claimed system is that the conversion to nitric oxide occur in the range of 600°C to 1700°C. The purpose of this limitation is to prevent nitrogen from other sources, such as the air, from being converted to nitric oxide and thereby distorting the measurement of nitric oxide derived from the nitrogen compounds of the sample.

The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance. Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. *See In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278. The Board erred by concluding otherwise.

D. Unexpected Results .

Because we reverse for failure to establish a *prima facie* case of obviousness, we need not reach Fine's contention that the Board failed to accord proper weight to the objective evidence of unexpected superior results. *Id.*

E. The "Flame" Claims .

[4] Claims 62, 68, 69, 79, 85 and 86 relate to the oxygen-rich flame conversion means of the claimed invention. These "flame" claims depend from either apparatus claim 60 or method claim 77. Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); *see also In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). In view of our conclusion that claims 60 and 77 are nonobvious, the dependent "flame" claims are also patentable.

Conclusion

The Board's decision affirming the Examiner's rejection of claims 60, 62, 63, 68, 69, 77, 79, 80, 85 and 86 of Fine's application as unpatentable over the prior art under 35 U.S.C. §103 is *REVERSED*.

Footnotes

Footnote *. The Solicitor argues that the contents of Attachment C of Fine's brief were not before the Board and may not properly be considered here. However, we need not rely on Attachment C. It is merely illustrative of the qualitative separation of nitrogen compounds which occurs in Fine's system. The fact that the various constituents exit at discrete intervals is shown by the specification which was before the Board and which may appropriately be considered on appeal. *See, e.g., Astra-Sjuco, A.B. v. United States Int'l Trade Comm'n*, 629 F.2d 682, 686, 207 USPQ 1, 5 (CCPA 1980) (claims must be construed in light of specification).

Dissenting Opinion Text

Dissent By:

Smith, circuit judge, dissenting.

I respectfully dissent. I am of the firm belief that the prior art references, relied upon by the PTO to establish its *prima facie* case of obviousness, in combination teach and suggest Fine's invention to one skilled in the art. Also, I firmly believe that Fine failed to rebut the PTO's *prima facie* case. On this basis, I would affirm the board's determination sustaining the examiner's rejection, pursuant to 35 U.S.C. §103, of Fine's claims on appeal before this court.

- End of Case -

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